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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,333	08/06/2003	John H. Crowe	010023-000150	8093

20350 7590 10/21/2005

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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/635,333	CROWE ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-61 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

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DETAILED ACTION  
Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-23, drawn to a first method, a method for loading a preservative into blood platelets using a solution having protein and preservative.

Group II, claims 24-33, drawn to a composition comprising platelets, water, protein and preservative.

Group III, claims 34-38, drawn to a second method, a method for processing platelets comprising suspending greater than  $10^8$  platelets/ml in a preservative solution and freeze-drying.

Group IV, claims 39-41, drawn to a third method, a method for preserving protein structure in platelets comprising loading platelets with a solution having protein and preservative, dehydrating the platelets to a residual water content of about 0.3gm/dry weight, storing and rehydrating the platelets.

Group V, claims 42-47, drawn to a second composition comprising freeze-dried platelets, protein and preservative.

Group VI, claims 48-55, drawn to a fourth method, a method for loading a preservative into platelets using a solution having protein and preservative and preventing a decrease in loading efficiency gradient.

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Group VII, claims 56–61, drawn to a fifth method, a method for loading a preservative into platelets comprising disposing platelets in a solution having a preservative and protein, preventing a decrease in a loading gradient in the loading of an oligosaccharide into the platelets.

An international or national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the of following combinations of categories;

- (1) a product and a process specially adapted for the manufacture of said product; or
  - (2) a product and a process of use of said product; or
  - (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
  - (4) a process and a apparatus specifically designed for carrying out said process; or
  - (5) a product, a process specially adapted for the manufacture of the said product and an apparatus specifically designed for carrying out said process.
- 37 CFR 1.475.

The groups of invention II and I fall within category (1), a product and a process specially adapted for the manufacture of said product.

PCT Rule 13 does not provide for multiple compositions or multiple methods of use within a single application. Thus, the first appearing composition is combined with a corresponding first method of use and the additional composition and method claims each constitute a separate group.

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In addition to the requirement that a group of inventions must belong to one of the specific categories provided by PCT Rule 13.2, the inventions in the category, such as a composition and a method of use or making of the composition, must have a special technical feature that unites them. See Patent Rules 1.475, where a special technical feature is a contribution OVER THE PRIOR ART.

Thus, the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features as demonstrated above. Since the composition AS CLAIMED is known in the art, see US 2001/046487, where a composition comprising platelets laded with BSA and trehalose is disclosed. Thus, no special technical feature unites these inventions in a category.

The expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art (PCT Rule 13.2). Thus, a feature found in the prior art cannot be considered to be a special technical feature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (571) 272-0926. The normal work schedule for Examiner Saucier is 8:30 AM to 6:00 PM Monday and Tuesday and 8:30 AM-12:30 PM on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The number of the Fax Center for the faxing of official papers is (571) 272-8300.

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a stylized flourish at the end.

Sandra Saucier  
Primary Examiner  
Art Unit 1651